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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,343	08/14/2002	Urban Schnell	1803-334-999	7095

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EXAMINER

BEISNER, WILLIAM H

ART UNIT PAPER NUMBER

1744

DATE MAILED: 11/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/070,343

Applicant(s)

SCHNELL ET AL.

Examiner

William H. Beisner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/5/2006 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1 and 13 both recite that "the walls of the channel adjacent to the fluid inlet form an angle of 100°-150° with the walls of the fluid inlet and the walls of the channel adjacent to the fluid outlet form an angle of 100° -150° with the walls of the fluid outlet". This claim limitation implies that all of the walls that form the channel are adjacent the inlet and outlet form an angle of 100° -150°, however, the originally filed specification and claims at best only convey to one of ordinary skill in the art at the time of filing the instant invention that the walls (7, 7', 7'',

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7''') of the body or frame (3) forming the channel form an angle of 100° -150° with respect to the inlet (10) and outlet (11). The channel is also formed by two additional walls (a bottom wall and top wall (See page 2, line 21, to page 3, line 5, of the specification) that are attached to either side of the body or frame (3). These walls also are considered walls of the channel and do not meet the instant claim language "the walls of the channel adjacent to the fluid inlet form an angle of 100°-150° with the walls of the fluid inlet and the walls of the channel adjacent to the fluid outlet form an angle of 100° -150° with the walls of the fluid outlet". As a result, the instant claim language is considered to be new matter since it encompasses a limitation wherein all of the walls that form the channel and are adjacent the inlet and outlet form an angle of 100° -150°.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1, 4-14, 16, 17 and 20-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petersen et al.(US 6,391,541) in view of Cheng et al.(US 6,071,394).

The reference of Petersen et al. discloses a cartridge (40) for conducting thermal cycling of fluids including a substantially planar and heat conducting wall (48); a light transparent wall (46) which is disposed substantially vertical to the heat conducting wall (48); a fluid inlet (41) for providing the cartridge with fluid; a fluid outlet (43) for draining fluid or gas from the cartridge; and a channel connecting the inlet and outlet defined by elements (50, 52 and 42) wherein the channel includes a protrusion defined by wall (59B) such that the channel between the inlet and outlet is longer than the shortest distance between the inlet and outlet and avoids bubbles in the measuring section (42) of the cartridge (See Figure 22 and column 13, line 56, to column 14, lines 5).

While the reference of Peterson et al. discloses an inlet (41) and outlet (43) communicated with channel (50, 52 and 42), the reference is silent as to the wall construction between the inlet and/or outlet and the channel (50, 52 and 42). Specifically, Claim 13 differs by

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reciting that the walls of the channel adjacent to the fluid inlet and the fluid outlet form an angle of 100-150 degrees.

The reference of Cheng et al. discloses a flow cell chamber (16) for a nucleic acid processing device that includes inlets and outlets (18b, 18c, 40b, 42b) and a channel (12) wherein the walls between the inlet and outlet and channel form an angle greater than 90 degrees and less than 180 degrees as shown in Figure 11b.

In view of this teaching and in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the flow cell device of the primary reference of Petersen et al. with angled walls at the inlets and/or outlets of the flow cell for the known and expected result of providing an alternative means recognized in the art to introduce and remove liquid within a nucleic acid processing device that includes a flow cell while providing the advantages associated with the structure of the chamber of the reference of Petersen et al.

With respect to claim 14, the device includes two opposing heat-conducting walls (48).

With respect to claim 17, the light transparent wall (46) includes first and second sections (57A and 57B) for introducing and collecting light from the cartridge.

With respect to claims 12, 20 and 22, the cartridge can have a thickness of between 0.5 and 5mm (See column 11, line 48) and a depth (W or L) 1 or 1.4 mm (See column 11, lines 45-50).

With respect to claims 11 and 21, the cartridge has a quotient range of width to depth of 1 to 10 (See column 11, lines 45-50).

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With respect to claim 1, the system includes cartridge (40) as discussed above with respect to claim 13 and also includes a thermocycling unit (147); a light source (216); a light detector (218) and a fluid providing unit (20).

With respect to claim 4, the light detector (218) is capable of detecting fluorescent light.

With respect to claim 5, the thermal cycling unit includes heat plates (190A and 190B).

With respect to claims 8 and 9, the transparent wall (46) includes first and second sections (57A and 57B) which are tilted.

With respect to claim 10, the thermal cycling unit includes heat plates (190A and 190B) which exert pressure on the cartridge when inserted between the plates (See Figure 23 and column 10, lines 32-45).

With respect to claims 23 and 24, use of the device as disclosed by the reference of Petersen et al. meets the method steps of these claims since the reference of Petersen et al. is using the device to perform and optically monitor a PCR reaction in chamber (42).

Claims 6, 7 and 16, differ by reciting that the container is "wedge" shaped.

While figure 23 of the reference of Petersen et al. appears to disclose a wedge-shaped container, the written disclosure is silent to this fact. However, in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the container as a wedge shape so as to ensure contact between the sidewalls of the container and the heat plates of the heating device.

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8. Claims 2, 3, 15, 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petersen et al.(US 6,391,541) in view of Cheng et al.(US 6,071,394) and Columbus et al.(EP 0 318 255).

The combination of the references of Petersen et al. and Cheng et al. has been discussed above.

Claims 2, 5, 15, 18 and 19 differ by reciting that the heat conducting walls are made of a metal foil.

The reference of Columbus et al. discloses that the use of aluminum foil wall (34) is conventional in the art for providing heat to a thermal cycling device (See column 7, line 54, to column 8, line 11).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to employ foil heating conducting walls in the system of the primary reference for the known and expected result of providing a high rate of thermal transfer to the PCR reagents within the processing chamber.

Response to Arguments

9. With respect to the rejection of Claims 1, 4-14, 16, 17 and 20-24 under 35 U.S.C. 103(a) as being unpatentable over Petersen et al.(US 6,391,541) in view of Cheng et al.(US 6,071,394), Applicants argue (See pages 6-8 of the response filed 7/10/2006) that the rejection is improper because the reference of Cheng et al. does not teach or suggest walls adjacent to the inlet or outlet having angles of 100-150 degrees. Applicants stress that the inlet and outlet of Cheng et al. are connected with the roof wall (42) and form an angle of 90 degrees.

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In response, the Examiner is of the position that the instant claim language does not structurally define over the combination of the references of Petersen et al. and Cheng et al. because tubing (18a, 18b, 18c) are considered part of the inlet and/or outlet of the device and the walls of the tubing are considered to be at the claimed angle with the angled walls of the channel (12) formed in the body of the device. These walls are considered to meet the claim language "adjacent". Note the language "adjacent" does not require that the walls are directly connected to the inlet. Something can be adjacent to something else without being connected to it. The instant claims do not require that the angles walls are directly connected to the inlet or outlet. Additionally, the instantly disclosed invention also includes walls connected to the inlet and/or outlet that do not meet the instant claim language (See the 35 USC 112, 1st paragraph, rejection above).

10. With respect to the rejection of Claims 2, 3, 15, 18 and 19 under 35 U.S.C. 103(a) as being unpatentable over Petersen et al.(US 6,391,541) in view of Cheng et al.(US 6,071,394) and Columbus et al.(EP 0 318 255), Applicants argue (See page 8 of the response filed 7/10/2006) that the rejection is improper for the same reasons with respect to the combination of the references of Petersen et al. and Cheng et al.

In response, the Examiner is of the position that the instant claim language does not define over the combination of the references of Petersen et al. and Cheng et al. for the same reasons as discussed above with respect to the rejection of claims 1, 4-14, 16, 17 and 20-24.

Conclusion

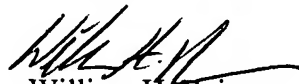
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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269.

The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys J. Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



William H. Beisner
Primary Examiner
Art Unit 1744

WHB